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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,660	09/15/2005	Jean-Louis Junien	102717.58257US	9879

23911 7590 10/19/2007
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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,660	JUNIEN ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed March 6, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. This Office Action is made NON-FINAL.

Claims

Claim Rejections - 35 USC § 102 – Anticipation (New Rejection)

Claims 12-13, 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al. (US 2003/0092736).

Cheng et al. disclose PPAR gamma and PPAR alpha agonist for the treatment of obesity. The PPAR alpha agonist includes fenofibrate and gemfibrozil (paragraph 0054). The compounds may be used in combination with compounds such as anti-diabetic agents metformin and/or lipid lowering agents such as PPAR alpha agonist fenofibrate and gemfibrozil (paragraph 0493). The amount of metformin may range from 500 to 2000 mg, encompassing claim 15. The metformin may be employed in a separate dosage form or in the same dosage form as the other active agents (paragraph 0175). The reference anticipates the instant claims insofar as it discloses a combination of metformin and PPAR alpha agonists such as fenofibrate in a method for treating obesity.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 12-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Obesity Research 1998) in view of Perry (US 5,942,500).

Lee et al. disclose metformin often promotes weight loss in patients with non-insulin-dependent diabetes mellitus by causing decreased food intake. The dosage ranged form 850 mg to 1700 mg. The reference differs from the instant claims insofar as it does not disclose treating obesity with a PPAR alpha agonist.

Perry discloses oral compositions to reduce dietary fats, which can act to aid in weight loss by preventing fats from being absorbed into the bloodstream cells in the body and is used as a general teaching to disclose the function of fibric acid derivatives. Fibric acid derivatives such as clofibrate, fenofibrate, and gemfibrozil, aid in the breakdown of fats (col. 3, lines 40-42). The reference differs from the instant claims insofar as it does not disclose metformin is used in combination with fibric acid derivatives to treat obesity.

Generally, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069,1072 (CCPA 1980); In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960). It would have been obvious to one of ordinary skill in the art to have combined the fibric acid derivatives with metformin motivated by the desire to

use two compounds that have been used to aid in weight loss in order to improve weight loss results.

2) Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Obesity Research 1998) in view of Chaput et al. (Biochemical and Biophysical Research Communications 2000).

The primary reference, Lee et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose treating obesity with a PPAR alpha agonist.

Chaput et al. disclose fenofibrate decreases body weight in fatty Zucker rats. The fibrate compounds improve lipidic control (paragraph 0015). The reference differs from the instant claims insofar as it does not disclose metformin is used in combination with fibric acid derivatives to treat obesity.

It would have been obvious to one of ordinary skill in the art to have combined the PPAR alpha agonist comprising compositions with the metformin compositions of the primary reference motivated by the desire to use two compounds that have been used to aid in weight loss in order to improve weight loss results, as supported by In re Kerkhoven, cited above.

3) Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Obesity Research 1998) in view of Piomelli et al. (US 2005/0101542).

The primary reference, Lee et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose treating obesity with a PPAR alpha agonist.

Piomelli et al. disclose combination therapy for controlling appetites leading to weight loss. PPAR alpha is postulated to play a role in obesity and diabetes. PPAR alpha agonist such as clofibrate, fenofibrate, bezafibrate, gemfibrozil and ciprofibrate are used in conjunction with a cannabinoid receptor to reduce body fat, body weight or to reduce appetites (paragraphs 0025-0026). The compounds also have these reducing effects when used alone. Depending upon the compound(s) and the above factors, for instance, the initial test dosage(s) may range, for example, from 0.1-50 mg per kg, preferably 1-25 mg per kg, most preferably 1-20 mg per kg body weight for each of the compound(s) (paragraph 218). This encompasses the dosages disclosed by claim 14. The reference differs from the instant claims insofar as it does not disclose metformin is used in combination with fibric acid derivatives to treat obesity.

It would have been obvious to one of ordinary skill in the art to have combined the PPAR alpha agonist comprising compositions with the metformin compositions of the primary reference motivated by the desire to use two compounds that have been used to aid in weight loss in order to improve weight loss results and to improve treatment of diabetes when the patient suffers from the symptom due to weight, as supported by In re Kerkhoven, cited above.

4) Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (US 2002/0173663).

Liu et al. teach a method of treating obesity (see claim 25) comprising the administration of an effective amount of a compound of Formula (I) (see page 24, right column, lines 10-11) which is a potent PPARα agonist (see page 6, paragraph 0079) and an effective amount of one or more other drugs (see page 24, right column, lines 12-13) such as metformin (see page 24, right column, lines 18-19). Liu et al. further disclose that the PPARα agonist compound of formula (I) is administered at a total daily dosage from about 1.0 mg to about 1000 mg (page 6, paragraph [0084], lines 9-10). The compound of formula (I) and other drugs may be administered contemporaneously (same meaning as simultaneously) or sequentially (page 7, paragraph 0093). The method may also comprise administering a compound of Formula (I) along with two other agents, which include metformin and PPAR alpha agonist such as gemifibrozil, clofibrate, fenofibrate and bezafibrate. The reference differs from the instant claims insofar as it does not disclose an example of a method using metformin and at least one of the recited PPAR alpha agonists together.

The reference is not anticipatory insofar as one must "pick and choose" from different lists of insulin sensitizers and cholesterol lowering agents. That being said, it would have been obvious in a self-evident manner to have selected metformin from one list and a fenofibric acid derivative from another, motivated by the unambiguous disclosure of each individually, and consistent with the basic principle of patent prosecution that a reference should be considered as expansively as is reasonable in determining the full scope of the contents within its four corners.

Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been also been obvious to use the PPAR alpha agonist such as fenofibric acid derivatives and metformin in a dosage ranging from 10 to 3000 mg a day motivated by the desire to use an effective amount of compound to achieve the desired result as supported by case law.

Claims 12-17 are rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
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Art Unit 1614

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